Medical devices

Development of a method for objectively monitoring the efficacy of analgesics on postoperative pain

Principal Investigator

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Project Outline

Outline of Technology Development

While many patients suffer postoperative pain, there is no method to objectively and automatically assessing it. Seventy-five percent of patients experience moderate or worse pain, and 39% report that moderate or worse pain continues after the first dose of analgesics have been administered. Overdoses of analgesics after an operation occur at the rate of 1 in 1000 patients, and there is a need for an effective pain-assessment system to control pain while preventing disastrous complications.

◆ We collected a total of 50,000 EEG data under pain, and by taking an AI approach to objectively assess pain, we were the first in the world to succeed in developing an algorithm that is 83% accurate using only EEG.

◆ Our aim is to prove its efficacy against postoperative pain in physician-led clinical trials and report the results.

Target Patients

◆ Patients undergoing operations under general anesthesia (3M/year in Japan; from Ministry of Health, Labour, and Welfare, Survey of medical Institutions)
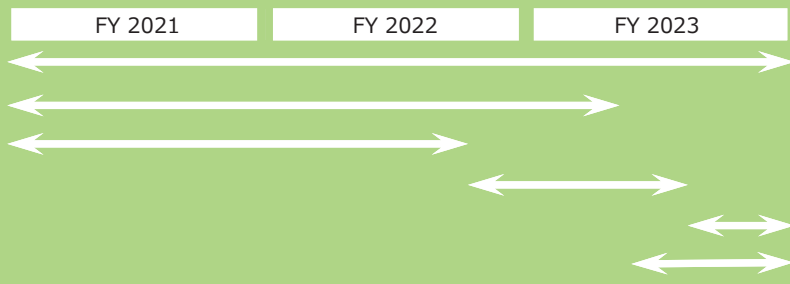
State of IP Rights

◆ 9 patent applications involving EEG feature values, discriminative models, and pain visualization (6 of which were already granted)

1. PCT/JP2016/052145 Pain Measurement Equipment and Pain Measurement System (Patent No. 6249432, Patent No. 6445634, CN107427248B)
2. PCT/JP2017/029991 Pain Estimation Equipment and Pain Estimation Method, Along with Classifications (Patent No. 6621538)
3. PCT/JP2018/028491 Application of Wavelet Transform of Time-Varying Signals
4. PCT/JP2018/026489 Classification of Pain using Sparse Modeling and Determination of Momentary Pain
5. PCT/JP2018/028300 Distinguishing Comfort & Discomfort (Patent No.6664715)
6. PCT/JP2018/025769 Pain Determination Using Trend Analysis, Medical Device Incorporating Machine Learning, Economic Discriminant Model, and IOT, Tailormade Machine Learning, and Novel Brainwave Feature Quantity for Pain Determination (Patent No. 6764205)
7. PCT/JP2020/017658 Reference Stimulus
8. PCT/JP2020/017655 System, Method, and Program for Amplifying Teaching Data used in Machine Learning
9. PCT/JP2021/048651 System, method, and program for estimating subjective evaluation by estimation subject

Road Map for Development

	FY 2021	FY 2022	FY 2023
● Pharmaceutical Affairs	←		→
● Exploratory physician-led clinical trial	←	→	
● Development of PMS-2	←	→	
● Preparation for physician-led clinical trial		←	→
● Physician-led clinical trial			← →
● Manufacturing Planning			← →

Development Progress

Development

Data Collection

Pain Assessment Assistance System PMS-2

Handheld EEG

Disposable Electrodes

Analysis

Create Model

Data Fitting

Successfully assessed surgery pain

Administer analgesics

Surgery → Postoperative electroencephalography Pain assessment → Trial completion

6 hours after leaving the operating room

★ Pain Score (PS) Measurement timing

* p = 0.0004

Before administration / 2 hours after administration

(Results) Change before analgesic administration - 2 hours after analgesic administration